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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/102,865	06/23/1998	SHANTHA T. RAJU	P1096R1	2304

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EXAMINER
SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	31

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/102,865	Raju
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above, claim(s) *10-24* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-9 and 25-29* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/12/2003 has been entered.

2. Claims 1-9,25-29 are under consideration.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-9,25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumpel et al. in view of Maras et al. (US Patent 5,834,251), prior art disclosed in the specification (pages 1,2,19-21) and Ward et al. (US Patent 6,165,745).

Kumpel et al. teach human monoclonal antibodies wherein the oligosaccharide profile differs depending on the culture conditions used to produce said antibodies. Kumpel et al. teach particular monoclonal antibodies wherein the vast majority of oligosaccharides found on said antibody is G2 (see abstract, Table 1, columns 1-3, and page 149, column 1, first incomplete paragraph). Said antibodies are in composition form wherein they are contained in a pharmaceutically acceptable carrier (eg. tissue culture media). The antibody 2B6 disclosed in Table 1 is an IgG1 antibody (see page 144, second column). Kumpel et al. teach that antibodies with predominantly G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 (see Figure 3). Kumpel et al. do not teach a G2 containing antibody preparation of the degree of purity recited in the claims. Kumpel et al. do not teach the molecules of claims 6-9 or the claimed articles of manufacture. Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein (see columns 12 and 16). Kumpel et al. teach that said enzyme is involved in

the production of G2 oligosaccharides (see abstract). The prior art recited in the specification (pages 1,2,19-21) discloses that the antibodies, immunoadhesions and chimeric molecules recited in claims 6-9 were known in the art, as was the clinical use of said molecules. While Klumpel et al. disclose that the antibodies would be expected to possess a shortened half-life in vivo (see page 150, first column), Ward et al. teach that antibodies with a reduced half live would have a variety of potential clinical uses (see column 5, last paragraph, continued on column 6). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Kumpel et al. teach particular monoclonal antibodies wherein the vast majority of oligosaccharides found on said antibody is G2 whilst Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein and Ward et al. teach that antibodies with a reduced half live would have a variety of potential clinical uses. One of ordinary skill in the art would have been motivated to do so because Kumpel et al. teach that antibodies with predominantly G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 whilst Ward et al. teach that antibodies with a shortened half life have a variety of potential clinical uses and the method taught by Maras et al, could have been used as an alternative method to produce G2 monoclonal antibodies or to produce a G2 antibody preparation with less G1 and GO oligosaccharides to further study the role of said oligosaccharides in antibody function. It would have been prima facie obvious to one of ordinary skill in the art to have created G2 oligosaccharide versions of the art known molecules recited in claims 6-9 because Kumpel et al. teach that antibodies with predominantly G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 whilst Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein (eg. to produce G2 oligosaccharide glycoproteins) and Ward et al. teach that antibodies with a reduced half live would have a variety of potential clinical uses . One of ordinary skill in the art would have been motivated to do the aforementioned in order to produce G2 versions of the aforementioned glycoproteins for potential clinical evaluation in view of the teachings of Ward et al. that antibodies with a shortened half life have a variety of potential clinical uses. Said G2 glycoproteins would have been produced as the claimed articles of manufacture

for use in clinical trials.

Regarding applicants comments, Kumpel et al. teach that antibodies with increased G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 (see Figure 3). Kumpel et al. teach that "The "hypergalactosylated" anti-D (LD BRAD-3) promoted greater FcgRI- and FcgRIII- mediated lysis of erythrocytes in ADCC assays than the anti-D with a lower galactose content (HD BRAD-3)(as shown in Figures 3 and 4)." (see page 149, first column, first complete paragraph). One of ordinary skill in the art would have been motivated to produce the claimed invention because Kumpel et al. teach that antibodies with predominantly G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 and the method taught by Maras et al, could have been used as an alternative method to produce G2 monoclonal antibodies or to produce a G2 antibody preparation with less G1 and GO oligosaccharides to further study the role of said oligosaccharides in antibody function. Regarding applicants comments about antibody half life, Ward et al. teach that antibodies with a shortened half life (or antibody conjugates) have a variety of potential clinical applications. The comments in Kumpel et al. regarding half life appear to be drawn to the specific use of unlabeled antibodies wherein the antibody is the specific antibody referred to in said paper (eg. Anti-D).

5. No claim is allowed.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan

can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644